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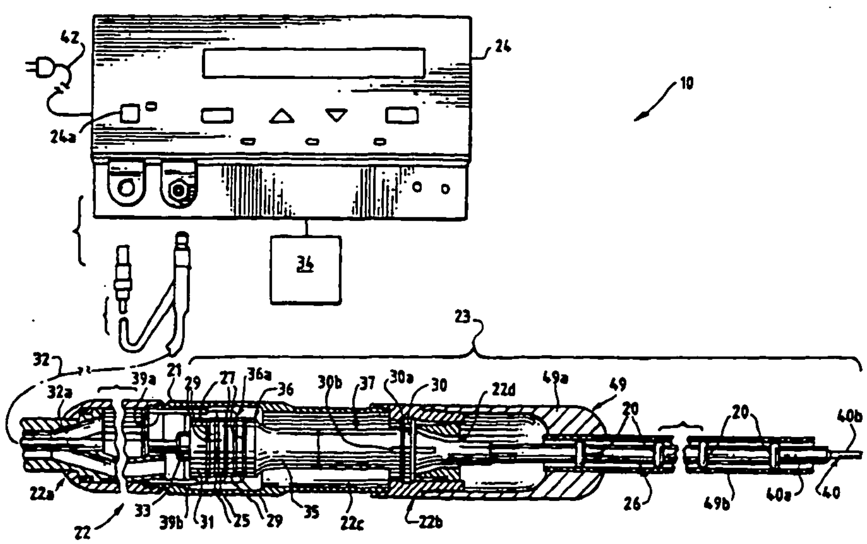

(57) Abstract

The present invention relates to devices and methods for improving blood flow to the heart of a patient. One device includes a transducer assembly (36) disposed in a housing. An end effector (40) is operatively coupled to the transducer assembly (36) and includes a channel-forming member. The channel-forming member is capable of creating channels in the heart of a patient. A method of improving the blood flow to the heart of a patient is also provided. The method includes the steps of providing a surgical device having an end effector (40), energizing the surgical device to cause the end effector (40) to vibrate, contacting the end effector (40) with a ventricular wall of the heart, advancing the end effector (40) into the ventricle wall, and creating a channel in the ventricle wall with the end effector (40).

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METHODS AND DEVICES FOR IMPROVING BLOOD FLOW TO A HEART OF A PATIENT

FIELD OF THE INVENTION

The present invention relates generally to medical devices and procedures. More particularly, it relates to methods and devices to improve the flow of blood to the heart by transmyocardial revascularization.

BACKGROUND OF THE INVENTION

Heart disease presents a major concern in western societies. Heart disease may cause chest pains, strokes, heart attacks, or even death. One form of heart disease is ischemic heart disease, a condition where the heart or myocardium does not receive an adequate nutritive blood supply. Typically, this condition occurs when the coronary arteries become blocked by plaque build-up on their inner walls.

When the plaque build-up of the coronary arteries hinders the flow of blood to the heart, the heart may become starved for nutrition and oxygen. As a result, the tissue of the heart may scar causing the heart to be weakened.

A number of approaches have been developed for treating heart disease. In less severe cases, proper diet and exercise may improve heart conditions. However, if diet and exercise are not effective, medication may be prescribed. If heart disease still persists, a minimally invasive or invasive procedure is usually performed.

There are several types of traditional medical procedures that may be used to improve blood supply to the heart. For example, coronary bypass surgery or percutaneous transluminal coronary angioplasty (PTCA) may be performed to increase blood flow to the heart.

Coronary bypass surgery involves open heart surgery where a surgeon removes a blood vessel from another part of the body, such as the leg or inside the chest wall, and uses the vessel to construct a detour around the blocked coronary artery. One end of the vessel is attached below the

blockage while the other end is attached above the blockage. As a result, blood may flow around the obstruction into the heart.

However, because bypass surgery typically requires extensive and complicated surgery, the patient needs to have adequate lung and kidney function in order to tolerate such surgery. This procedure also requires postoperative care in an intensive care unit, seven to ten days in the hospital, and several months of recovery. Other complications, such as strokes, heart attacks, or infections, may develop during or as a consequence of the surgery. In addition, the blood vessel may close or become blocked several months after the surgery.

In PTCA, a surgeon inserts a thin wire through a small incision in an arm or leg artery of a patient and threads the wire toward the blocked area of the coronary artery. Next, a guide catheter may be passed over the wire and a balloon-tipped catheter is usually threaded through the guide catheter. When the balloon-tipped catheter reaches the blockage area, the balloon is inflated to compress the plaque build-up against the coronary artery walls widening the artery for blood flow. The balloon-tipped catheter may then be deflated and withdrawn from the patient.

If the artery closes or threatens to close, a balloon catheter having a mesh stent may be used. As the stented balloon inflates, the mesh of the stent expands and remains in place to hold the artery open after the balloon catheter has been removed.

More recently, Laser Transmyocardial Revascularization (LTR) has been used as an alterative to coronary bypass surgery or PTCA. This technique is used to supplement the blood supply received by the heart by providing the myocardium direct access to blood in the ventricle chamber. In one known approach, LTR is performed using a high power, pulsed, CO_2 laser. The laser may be operated to create a channel from the ventricle to the myocardium. The laser is fired against the outer ventricle surface of the heart when the ventricle is full of blood. The blood in the ventricle acts as a backstop preventing the energy of the laser from penetrating through the other side of the ventricle or damaging nearby tissue.

After a channel is formed, blood may flow through the resulting channel from the ventricle into the myocardium.

However, the cost of the laser is quite high, as is the cost of the procedure. The laser is ordinarily quite large and takes up significant space in the operating room. In addition, LTR is not always easily adaptable for thoracoscopic heart surgery and usually requires a 2.5 cm mini-thoracotomy. Furthermore, LTR ordinarily requires an EKG to synchronize the firing of the laser when the heart is full of blood to absorb the laser beam.

Ultrasonic devices are also known for assisting a surgeon in cutting tissue. For example, U.S. Patent No. 5,449,370 entitled "Blunt Tipped Ultrasonic Trocars," which is herein incorporated by reference, discloses a trocar to puncture an abdominal wall of a patient. U.S. Patent No. 5,324,299 entitled "Ultrasonic Scalpel Blade And Method Of Application," which is incorporated herein by reference, discloses an ultrasonic device including a blade portion having a recess that defines a hook for grasping and tensioning loose tissue to facilitate cutting. U.S. Patent No. 5,322,055 entitled "Clamp Coagulator/Cutting System For Ultrasonic Surgical Instruments," which is incorporated herein by reference, also discloses a surgical instrument for cutting tissue. The instrument includes an ultrasonic blade for use with a clamp to improve tissue cutting.

Accordingly, there is a need for devices and methods to treat heart disease. It would be beneficial to provide devices and methods to achieve a more effective treatment of heart disease with better results. It would also be desirable to provide a cost-effective and minimally intrusive procedure to improve blood flow to the heart.

SUMMARY OF THE INVENTION

The present invention provides methods and devices to treat certain types of heart disease and to improve blood flow to tissue in a heart of a patient. The devices and methods of the present invention provide an efficient and minimally intrusive procedure to improve the blood supply to

the myocardium of the heart. This is accomplished by a form of transmyocardial revascularization (TMR) where the heart is ultrasonically pierced to create a channel from a ventricle to the myocardium of the heart. Channels of varying dimension may be created in order to minimize lateral spread of coagulation.

The devices and methods in accordance with the present invention may be useful for patients with advanced heart disease or poor vascular systems who may not be candidates for PTCA. The devices can be inserted through an incision in the chest of the patient. In addition, the devices and methods may be suitable for patients unable to have coronary bypass surgery.

One ultrasonic device in accordance with the present invention includes a transducer assembly adapted to vibrate at an ultrasonic frequency in response to electrical energy. An end effector is adapted to receive the ultrasonic vibrations from the transducer assembly and to transmit the vibration to the distal end of the end effector which is disposed at an antinode. The end effector is adapted to be placed in contact with a heart of a patient to create a channel.

One method of improving blood flow in accordance with the present invention includes the steps of inserting an end effector into a patient, energizing a transducer assembly to transmit ultrasonic vibration to vibrate an end of an end effector, and advancing the end effector to an area near a heart of a patient. The method further includes the steps of contacting the heart with the end effector to create a channel in the heart, and withdrawing the end effector from the heart.

Another surgical device in accordance with the present invention includes a non-optical end effector formed about an axial center line to create channels in selected tissue of a patient. A transducer assembly is adapted to vibrate at an ultrasonic frequency in response to electrical energy is to actuate the end effector.

Another method in accordance with the present invention includes the steps of providing a surgical device having an end effector,

energizing the surgical device to cause the end effector to vibrate, and contacting the end effector with a ventricular wall of patient. The method further includes the steps of advancing the end effector into the ventricle wall, and creating a channel in the ventricular wall with the end effector.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory and are intended to provide further explanation of the invention as claimed.

The invention, together with further objects and attendant advantages, will best be understood by reference to the following detailed description of the presently preferred embodiment of the invention, taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a diagrammatic view of one preferred embodiment of a probe assembly of a medical device creating channels in a heart of a patient;

FIG. 2 is a fragmentary view and in partial cross-section of a preferred embodiment of a medical system according to the present invention;

FIG. 3 is a fragmentary exploded perspective view of the end effector of the medical system of FIG. 2;

FIGS. 4-10 are fragmentary perspective views of preferred embodiments of tips of an end effector of FIG. 2;

FIGS. 11-12 are fragmentary perspective views of other preferred embodiments of an end effector of the medical system according to the present invention; and

FIGS. 13a-b are fragmentary perspective views of other preferred embodiments of an end effector of a medical system according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Before explaining the present invention in detail, it should be noted that the invention is not limited in its application or use to the details of construction and arrangement of parts illustrated in the accompanying drawings and description, because the illustrative embodiments of the invention may be implemented or incorporated in other embodiments, variations and modifications, and may be practiced or carried out in various ways. Furthermore, unless otherwise indicated, the terms and expressions employed herein have been chosen for the purpose of describing the illustrative embodiments of the present invention for the convenience of the reader and are not for the purpose of limitation.

Referring now to the drawings in detail, and particularly to FIG. 1, a preferred embodiment of an end effector 40 of a surgical or surgical system 10 is shown forming one or more channels 12a (shown in phantom) in a heart 12 of a patient. The end effector 40, starting from an outer ventricular wall 14, tunnels or burrows through the outer wall 14 and inner wall 11 of the heart 12 into a heart cavity or ventricle 16 to form the channels 12a.

The channels 12a provide a path for blood to flow into the myocardium 18 of the heart 12 from the heart cavity 16. The outer wall 14 of the heart 12 is sealed by coagulated blood 19 once the end effector 40 has been withdrawn. A viewing device 17 may be employed to allow a user or surgeon to view and monitor the procedure. The viewing device 17 may be attached to an eye piece, a monitor, a video system, or the like. It is contemplated that the surgical system 10 may also create channels in other areas of the heart as well as other tissue of a patient.

Referring now to FIG. 2, a preferred embodiment of a surgical system 10 is illustrated. The surgical system 10 generally includes a generator 24, a handpiece assembly 22, and an acoustic assembly 23. The generator 24 sends electrical signals through a cable 32 at a selected amplitude, frequency, and phase determined by a control system (not shown) of the generator 24. As will be further discussed, the signal causes one or

more piezoelectric elements 29 of the acoustic assembly 23 to expand and contract, thereby converting the electrical energy into mechanical motion. The mechanical motion results in longitudinal waves of ultrasonic energy that propagate through the acoustic assembly 23 in an acoustic standing wave to vibrate the acoustic assembly 23 at a selected frequency and amplitude. The end effector 40 at the distal end of the acoustic assembly 23 is placed in contact with tissue of the patient to transfer the ultrasonic energy to the tissue. The cells of tissue in contact with the end effector of the acoustic assembly 23 will move with the end effector and vibrate.

As the end effector couples with the tissue, thermal energy or heat is generated as a result of internal cellular friction with the tissue. The heat is sufficient to break protein hydrogen bonds, causing the highly structured protein (i.e., collagen and muscle protein) to denature (i.e., become less organized). As the proteins are denatured, a sticky coagulum forms to seal or coagulate small blood vessels when the coagulum is below 100°C. Deep coagulation of larger blood vessels results when the effect is prolonged.

The transfer of the ultrasonic energy to the tissue causes other effects, including mechanical tearing, cutting, cavitation, cell disruption, and emulsification. The amount of cutting as well as the degree of coagulation obtained varies with the vibrational amplitude of the end effector, the amount of pressure applied by the user, and the sharpness of the end effector. The end effector of the acoustic assembly 23 in the surgical system 10 tends to focus the vibrational energy of the system onto tissue in contact with the end effector, intensifying and localizing thermal and mechanical energy delivery. As a result, the end effector 40 may create channels through the heart 12 of a patient while controlling the coagulation of the tissue to reduce bleeding.

As illustrated in FIG. 2, the generator 24 includes a control system integral to the generator 24, a power switch 24a, and a triggering mechanism 34. The power switch 24a controls the electrical power to the generator 24, and when activated by the triggering mechanism 34, the generator 24 provides energy to drive the acoustic assembly 23 of the

surgical system 10 at a predetermined frequency and to drive the end effector at a predetermined vibrational amplitude level. The generator 24 may drive or excite the acoustic assembly 23 at any suitable resonant frequency of the acoustic assembly 23.

When the generator 24 is activated via the triggering mechanism 34, electrical energy may be continuously applied by the generator 24 to a transducer assembly 36 of the acoustic assembly 23. A phase lock loop in the control system of the generator 24 monitors feedback from the acoustic assembly 23. The phase lock look adjusts the frequency of the electrical energy sent by the generator 24 to match a preselected harmonic frequency of the acoustic assembly 23. In addition, a second feedback loop in the control system maintains the electric current supplied to the acoustic assembly 23 at a preselected constant level in order to achieve substantially constant vibrational amplitude at the end effector of the acoustic assembly 23.

The electrical signal supplied to the acoustic assembly 23 will cause the distal end to vibrate longitudinally in the range of, for example, approximately 20 kHz to 100 kHz, and preferably in the range of 54 kHz to 56 kHz, and most preferably at about 55.5 kHz. The amplitude of the acoustic vibrations at the end effector may be controlled by, for example, controlling the amplitude of the electrical signal applied to the transducer assembly of the acoustic assembly 23 by the generator 24.

As noted above, the triggering mechanism 34 of the generator 24 allows a user to activate the generator 24 so that electrical energy may be continuously supplied to the acoustic assembly 23. In one embodiment, the triggering mechanism 34 preferably comprises a foot activating switch that is detachably coupled or attached to the generator 24 by a cable or cord. In another embodiment, a hand switch may be incorporated in the handpiece assembly 22 to allow the generator 24 to be activated by a user.

The generator 24 also has a power line 42 for insertion in an electrosurgical unit or conventional outlet. It is contemplated that the generator 24 may also be powered by a direct current (DC) source, such as a

battery. The generator 24 may be any suitable generator, such as Model No. GEN01 available from Ethicon Endo-Surgery, Inc.

Referring still to FIG. 2, the handpiece assembly 22 includes a multi-piece housing or an outer casing 21 adapted to isolate the operator from vibration of the acoustic assembly 23. The housing 21 is preferably cylindrically shaped and is adapted to be held by a user in a conventional manner, but may be any suitable shape or size which allows it to be grasped by the user. While a multi-piece housing 21 is illustrated, the housing 21 may comprise a single or unitary component.

The housing 21 of the handpiece assembly 22 is preferably constructed from a durable plastic, such as Ultem®. It is also contemplated that the housing 21 may be made from a variety of materials including other plastics (i.e., liquid crystal polymer LCP), nylon, or polycarbonate). A suitable handpiece assembly 22 may be Model No. HP050, available from Ethicon Endo-Surgery, Inc.

The handpiece assembly 22 generally includes a proximal end 22a, a distal end 22b, and centrally disposed axial opening or cavity 22c extending therein. The distal end of the handpiece assembly 22 includes an opening 22d configured to allow the acoustic assembly 23 of the surgical system 10 to extend therethrough, and the proximal end of the handpiece assembly 22 is coupled to the generator 24 by a cable 32. The cable 32 may include air ducts or vents 32a to allow air to be introduced into the handpiece assembly 22 to cool the transducer assembly of the acoustic assembly 23.

Referring to FIG. 2, the acoustic assembly 23 generally includes a transducer stack or assembly 36, and a transmission component or working member. The transmission component may include a mounting device 37, a transmission rod or waveguide 26, and an end effector or applicator 40. The transducer assembly 36, mounting device 37, transmission rod 26, and the end effector 40 are preferably acoustically tuned such that the length of each component is an integral number of one-half system wavelengths ($\lambda/2$) where the system wavelength symbol is the

wavelength of a preselected or operating longitudinal frequency f of the acoustic assembly 23. It is also contemplated that the acoustical assembly 23 may incorporate any suitable arrangement of acoustic elements For example, the acoustic assembly 23 may comprise a transducer assembly and an end effector (i.e., the acoustic assembly 23 may be configured without a mounting device and a transmission rod).

The transducer assembly 36 of the acoustic assembly 23 converts the electrical signal from the generator 24 into mechanical energy that results in longitudinal vibratory motion of the end effector 40 at ultrasonic frequencies. When the acoustic assembly 23 is energized, a vibratory motion standing wave is generated through the acoustic assembly 23. The amplitude of the vibratory motion at any point along the acoustic assembly 23 depends on the location along the acoustic assembly 23 at which the vibratory motion is measured. A minimum or zero crossing in the vibratory motion standing wave is generally referred to as a node (i.e., where axial motion is usually minimal and radial motion is usually small), and an absolute value maximum or peak in the standing wave is generally referred to as an antinode. The distance between an antinode and its nearest node is on-quarter wavelength ($\lambda/4$).

As shown in FIG. 1, the transducer assembly 36 of the acoustic assembly 23, which is known as a "Langevin stack", generally includes a transduction portion 36a, a first resonator 31, and a second resonator 35. The transducer assembly 36 is preferably an integral number of one-half system wavelengths ($\lambda/2$) in length. It is to be understood that the present invention may be alternatively configured to include a transducer assembly comprising a magnetostrictive, electromagnetic, or electrostatic transducer.

The distal end of the first resonator 31 is connected to the proximal end of the transduction section 36a and the proximal end of the second resonator 35 is connected to the distal end of the transduction portion 36a. The first and second resonators 31 and 35 are preferably fabricated from titanium, aluminum, steel, or any other suitable material. The first and

second resonators 31 and 35 have a length determined by a number of variables, including the thickness of the transduction section 36a, the density and modulus of elasticity of material used in the resonators 31 and 35, and the fundamental frequency of the transducer assembly 36. The second resonator 35 may be tapered inwardly from its proximal end to its distal end to amplify the ultrasonic vibration amplitude.

The transduction section 36a of the transducer assembly 36 preferably comprises a piezoelectric section of alternating positive electrodes 25 and negative electrodes 27, with piezoelectric elements 29 alternating between the electrodes 25 and 27. The piezoelectric elements 29 may be fabricated from any suitable material, such as, for example, lead zirconate-titanate, lead meta-niobate, lead titanate, or ceramic piezoelectric crystal material. Each of the positive electrodes 25, negative electrodes 27, and piezoelectric elements 29 may have a bore extending through the center. The positive and negative electrodes 25 and 27 are electrically coupled to wires 39a and 39b, respectively. Wires 39a and 39b transmit electrical signal from the generator 24 to the electrodes 25 and 27.

As shown in FIG. 2, the piezoelectric elements 29 are held in compression between the first and second resonators 31 and 35 by a bolt 33. The bolt 33 preferably has a hand, a shank, and a threaded distal end. The bolt 33 is inserted from the proximal end of the first resonator 31 through the bores of the first resonator 31, the electrodes 25 and 27, and the piezoelectric elements 29. The threaded distal end of the bolt 33 is screwed into a threaded bore on the proximal end of second resonator 35.

The piezoelectric elements 29 are energized in response to the electrical signal supplied from the generator 24 to produce an acoustic standing wave in the acoustic assembly 23. The electrical signal causes disturbances in the piezoelectric elements 29 in the form of repeated small displacements resulting in large compression and forces within the material. The repeated small displacements cause the piezoelectric elements 29 to expand and contract in a continuous manner along the axis of the voltage gradient, producing high frequency longitudinal waves of ultrasonic energy.

The ultrasonic energy is transmitted through the acoustic assembly 23 to the end effector.

The mounting device 37 of the acoustic assembly 23 has a proximal end, a distal end, and may have a length substantially equal to an integral number of one-half system wavelengths. The proximal end of the mounting device 37 is preferably axially aligned and coupled to the distal end of the second resonator 35 by an internal threaded connection near an antinode. (For purposes of this disclosure, the term "near" is defined as "exactly at" or "in close proximity to".) It is also contemplated that the mounting device 37 may be attached to the second resonator 35 by any suitable means, and that the second resonator 35 and the mounting device 37 may be formed as a single or unitary component.

The mounting device 37 is connected or mounted to the housing 21 of the handpiece assembly 22 near a node. The mounting device 37 may include an integral ring 30 disposed around its periphery. The integral ring 30 is preferably disposed in an annular groove formed in the housing 21 of the handpiece assembly 22 to mount the mounting device 37 to the housing 52. A compliant member or material 30a, such as a pair of silicone O-rings attached by stand-offs, may be placed between the annular groove of the housing 21 in the integral ring 30 of the mounting device 37 to reduce or prevent ultrasonic vibration from being transmitted from the mounting device 37 to the housing 21.

The mounting device 37 may be secured in a predetermined axial position by a plurality of pins 30b, preferably four. The pins are disposed in a longitudinal direction 90 degrees apart from each other around the outer periphery of the mounting device 37. The pins are coupled to the housing 22 of the handpiece assembly 23 and are disposed through notches in the integral ring 30 of the mounting device 37. The pins are preferably fabricated from stainless steel.

The mounting device 37 is preferably configured to amplify the ultrasonic vibration amplitude that is transmitted through the acoustic assembly 23 to the distal end of the end effector 40. In one preferred

embodiment, the mounting device 37 comprises a solid, tapered horn. As ultrasonic energy is transmitted through the mounting device 37, the velocity of the acoustic wave transmitted through the mounting device 37 is amplified. It is contemplated that the mounting device may be any suitable shape, such as, for example, a stepped horn, a conical horn, an expediential horn, a unitary gain horn, or the like.

The distal end of the mounting device 37 is coupled to the proximal end of the transmission rod 26. It is contemplated that the transmission rod 26 be attached to the mounting device 37 by any suitable means, such as, for example, an internal threaded connection. The mounting device 37 is preferably coupled to the transmission rod 26 near an antinode.

The transmission rod 26 may, for example, have a length substantially equal to an integral number of one-half system wavelengths ($\lambda/2$). The transmission rod 26 may be preferably fabricated from a solid core shaft constructed out of material which propagates ultrasonic energy efficiently, such as titanium alloy (i.e., Ti-6Al-4V) or an aluminum alloy. It is contemplated that the transmission rod 26 may be fabricated from any other suitable material. The transmission rod 26 may also amplify the mechanical vibrations transmitted through the transmission rod 26 to the end effector 40 as is well known in the art.

As illustrated in FIG. 2, the transmission rod 26 includes stabilizing silicone rings or compliant supports 20 positioned at a plurality of nodes. The silicone rings 20 dampen undesirable vibration and isolate the ultrasonic energy from a sheath 49 assuring the flow of ultrasonic energy in a longitudinal direction to the distal end of the end effector 40 with maximum efficiency.

As shown in FIG. 2, the sheath 49 is coupled to the distal end of the handpiece assembly 22. The sheath 49 generally includes an adapter or nose cone 49a and an elongated tubular member 49b. The tubular member 49b is attached to the adapter 49a and has an opening extending longitudinally therethrough. The sheath 49 may be threaded or snapped onto the distal end of the housing 21. The transmission rod 26 of the acoustic

assembly 36 extends through the opening of the tubular member 49b and the silicone rings 30 isolate the transmission rod 26 from the tubular member 49b.

The adapter 49a of the sheath 49 is preferably constructed from Ultem® and the tubular member 49b is fabricated from stainless steel. Alternatively, the transmission rod 26 may have a polymeric material that surrounds the transmission rod 26 to isolate it from outside contact.

The distal end of the transmission rod 26 may be coupled to the proximal end of the end effector 40 by an internal threaded connection, preferably near an antinode, as shown in FIG. 3. It is contemplated that the end effector 40 may be attached to the transmission rod 26 by any suitable means, such as a welded joint or the like. Although the end effector 40 may be detachable from the transmission rod 26, it is also contemplated that the end effector 40 and the transmission rod 26 may be formed as a single unit.

The end effector 40 may have a distal region 40b having a smaller cross-sectional area than a proximal region 40a thereof, thereby forming a vibrational amplitude step up junction. The step up junction acts as a velocity transformer as known in the art, increasing the magnitude of the ultrasonic vibration transmitted from the proximal region to the distal region of the end effector 40.

The end effector 40 may have a length substantially equal to an integral multiple of one-half system wavelengths ($\lambda/2$). The end effector 40 may be disposed at an antinode in order to produce the maximum longitudinal deflection of the distal end. When the transducer assembly 36 is energized, the distal end of the end effector 40 is configured to move longitudinally in the range of, for example, approximately 10 to 500 microns peak-to-peak, and preferably in the range of 30-100 microns at a predetermined vibrational frequency, an most preferably about 90 microns.

The end effector 40 is preferably made from a solid core shaft constructed of material which propagates ultrasonic energy, such as, for example, a titanium alloy (i.e., Ti-6Al-4V) or an aluminum alloy. It will be recognized that the end effector 40 may be fabricated from any suitable

material. It is also contemplated that the end effector may have a surface treatment to improve the delivery of energy and desired tissue effect. For example, the end effector 40 may be micro-finish, coated, plated, etched, grit-blasted, roughened or scored to enhance coagulation in tissue and to reduce adherence and blood to the end effector. Additionally, the end effector 40 may be sharpened or shaped to enhance its energy transmission characteristics. For example, the end effector 40 may be blade shaped, hook shaped, or ball shaped.

Referring again to FIG. 3, the end effector 40 of the surgical system 10 generally includes a channel creating tip 50. The tip 50 of the end effector 40 may be used to channel or burrow through the tissue of a heart of a patient when the end effector 40 is energized. Preferably, the tip 50 and end effector 40 are symmetrical about a center line "A".

Referring now to FIGS. 4-8, a number of embodiments of an end effector 40 for creating channels in a heart of a patient are illustrated. In FIG. 4, the distal end 50a of the end effector 40 has a substantially round configuration. With this arrangement, the distal end 50a of the end effector 40 can create channels in the heart of a patient while minimizing trauma, tissue damage, and cutting. In FIG. 5, the distal end 50b of the end effector 40 has a substantially pointed or conical shape. With this configuration, the distal end 50b of the end effector 40 can be utilized to minimize trauma and allow for easier tissue penetration when creating channels in the heart of the patient. In FIG. 6, the distal end 50c of the end effector 40 has a substantially blunt, flat, or square configuration. With this embodiment, the distal end 50c of the end effector 40 can minimize tissue displacement and maximize tissue cutting and removal when creating channels in the heart of the patient. In FIG. 7, the distal end 50d has a substantially beveled or tapered configuration. The edges at the juncture of the sides of the tapered section of the distal end 50d provide narrow cutting edges and the broad surfaces therebetween increase the amount of energy delivered by the edges to increase coagulation or hemostasis. In FIG. 8, the distal end 50e of the end effector 40 has a substantially pyramidal or triangular configuration.

The edges at the juncture of the sides of the triangular-shaped distal end 50e provide narrow cutting edges to facilitate penetration and advancement, while the broad surfaces therebetween afford coagulation surfaces when creating channel in the heart of the patient. As those skilled in the art will appreciate, the blunt or flat tips may tend to create more coagulation or hemostasis than the pointed tips because of slower penetration.

Referring now to FIGS. 9-10, 13a, and 13b, alternative embodiments of the end effector 40 are illustrated. In FIG. 9, the distal end 41 of the end effector 40 has multiple steps 41 to maximize tissue removal when creating channels in the heart of the patient. In FIG. 10, the distal end 45 of the end effector 40 has a stepped shoulder 43 having any suitable shaped tip 45. The stepped shoulder can be used as a indicator of penetration depth and to prevent over insertion. In FIG. 13a, the distal end 40a of the end effector 40 has a hollow tubular tip to core out tissue 40a. In FIG. 13b, the distal end 61 of the end effector has a larger diameter than the shaft 63 to promote a constant diameter channel and to prevent formation of channels having cone-shaped cross-sections. It is also contemplated that the end effector 40 may also be stepped or tapered inwardly or have a receding diameter.

Referring now to FIGS. 11-12, other embodiments of an end effector 40 having a plurality of channel-forming members are illustrated. As shown in FIG. 11, the end effector 54 may include a plurality of parallel channel-forming members 52 extending from a proximal section to simultaneously create a plurality of channels in the heart. The channel-forming members 52 may be positioned in any suitable arrangement (i.e. symmetrical or asymmetrical) to create a desired pattern. The end effector 54 preferably has a length of one-half wavelength ($\lambda/2$) and the channel-forming members 52 and proximal section each have a length of a quarter wavelength ($\lambda/4$). The junction between the channel-forming member 52 and proximal section is preferably located at a node. The distal end of end effector 54 may be vibrated by the acoustic assembly 23.

As illustrated in FIG. 12, the end effector 51 may also have a plurality of channel-forming members 53 positioned in parallel relationship with the ends thereof arranged in a staggered or step configuration. The channel-forming members 53 have a length of differing number of an integer (x,y,z) number of half wavelengths. The junction between the channel-forming members 53 and the proximal section is located at an antinode. The proximal portion of end effector 51 is configured to have a length of an integer number (n) of half wavelengths. The distal ends of the channel-forming members 53 may be vibrated by the acoustic assembly 23.

The end effector of the surgical system 10 may also include a plurality of channel-forming members of substantially the same or of different lengths. For example, as illustrated in FIG. 11, the length of the channel-forming members 52 of the end effector 54 are substantially the same length. On the other hand, the length of the channel-forming members 53 of the end effector 51 may differ by about one-half wavelength as shown in FIG. 12. It is also contemplated that the channel-forming members 52 may be any suitable length. The plurality of channel-forming members allow multiple channels to be created at the same time, reduce the time it takes to create multiple channels with a single tip, maintain predetermined spacing between channels, and allow the end effector to be inserted into the tissue at a desired angle.

The use of the medical device 10 will now be described with reference to FIGS. 1 and 2. Initially, the handpiece assembly 22 is connected to the generator 24 in an unarmed state. The generator 24 then measures the initial parameters of the acoustic assembly 23 (i.e. without an end effector 40) and arms the system (i.e. without an end effector 40). The handpiece assembly 22 is then in a ready state at which point the surgeon may trigger the power using the triggering mechanism 34. The surgeon places the handpiece assembly 22 at the insertion site. Ultrasonic energy is delivered to the distal end 40b of the end effector 40 while the surgeon applies a minimal force to the acoustic assembly 23 until the acoustic assembly 23 is inserted into the patient.

The end effector 40 of the surgical system 10 is then inserted into an incision or port made in the chest of a patient. The end effector 40 is guided to a desired area of the heart 12 as shown in FIG. 1. The surgical system 10 is then energized to activate the end effector 40. The end effector 40 penetrates through the outer wall 14 of the heart 12 and through the myocardium 18 and into the ventricle chamber 16 to create a channel 12a. It is believed that the active or energized distal end 40b of the end effector 40 causes mechanical pressure and tissue cavitation which causes the end effector 40 to create channels in the tissue. The end effector 40 is then withdrawn. The outer wall 14 of the heart 12 may be sealed by coagulated blood 19 once the end effector 40 has been withdrawn. The viewing device 17, such as a thoracoscope, may be used to observe the procedure.

A plurality of channels 12a are generally formed in the heart 12. The channels 12a are preferably approximately 1mm in diameter. These channels 12a provide a flow path for blood into the myocardium 18 from the ventricular chamber 16. It is contemplated that the diameter of the channels 12a may be any suitable size without departing from the spirit and scope of the invention.

It is also contemplated that the end effector 40 may be inserted through a laparoscopic or thoracoscopic port to create the channels. For example, the end effector 40 may be inserted through a 5mm thoracic port.

The devices and methods of the present invention allow channels to be formed in the heart to enhance the flow of blood to the heart muscle in order to improve various types of heart disease. The channels allow entry of reviving, oxygen-rich blood to pass from the ventricle chamber into the myocardium 85 of the heart 81.

The devices in accordance with the present invention may be inserted through an incision or a port in the chest of a patient, or may be inserted into the vascular system of a patient to allow access to an area in need of increased blood circulation due to heart disease. The devices and methods of the present invention may be useful for patients with advanced heart disease or poor vascular systems who might not otherwise be

candidates for angioplasty procedures. In addition, it may be suitable for those too sick for bypass surgery, as well as for those patients with myocardium at risk.

Although the present invention has been described in detail by way of illustration and example, it should be understood that a wide range of changes and modifications can be made to the preferred embodiments described above without departing in any way from the scope and spirit of the invention. Thus, the described embodiments are to be considered in all respects only as illustrative and not restrictive, and the scope of the invention is, therefore, indicated by the appended claims rather than the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

WHAT IS CLAIMED IS:

1. An ultrasonic device for use in transmyocardial revascularization comprising:

a transducer assembly adapted to vibrate at an ultrasonic frequency in response to electrical energy;

a mounting device having a first end and a second end, the mounting device adapted to receive ultrasonic vibration from the transducer assembly and to transmit the ultrasonic vibration from the first end to the second end of the mounting device, the first end of the mounting device coupled to the transducer assembly;

a transmission rod having a first end and a second end, the transmission rod adapted to receive ultrasonic vibration and to transmit the ultrasonic vibration from the first end to the second end of the transmission rod, the first end of the transmission rod coupled to the second end of the mounting device; and

an end effector having a first end and a second end, the end effector adapted to receive the ultrasonic vibration and to transmit the vibration from the first end to the second end of the end effector, the second end of the end effector being disposed near an antinode and the first end of the end effector coupled to the second end of the transmission rod, wherein the end effector is adapted to be placed in contact with a heart of a patient to create a channel.

2. The device of claim 1 wherein the end effector has a length between 1.5 cm and 2.5 cm.

3. The device of claim 1 wherein the end effector has a diameter between .25 cm and 2 cm.

4. The device of claim 1 wherein the end effector has a plurality of channel-forming members, each of the channel-forming members having an end disposed near an antinode.

5. The device of claim 4 wherein the ends of the channel-forming members are arranged at an angle to a center line extending through the handpiece.

6. A method of improving blood flow comprising the steps of:

inserting an end effector into a patient;

energizing a transducer assembly to transmit ultrasonic vibration to vibrate an end of a end effector;

advancing the end effector to an area near a heart of a patient;

contacting the heart with the end effector to create a channel in the heart; and

withdrawing the end effector from the heart.

7. The method of claim 6 further repeating the steps of advancing, contacting and withdrawing to form a plurality of channels in the heart.

8. An ultrasonic device for use in transmyocardial revascularization comprising:

a transducer assembly adapted to vibrate at an ultrasonic frequency in response to electrical energy; and

a transmission component including means adapted to receive the ultrasonic vibration and to transmit the vibration to the distal end of the end effector, the distal end of the end effector disposed at an antinode; and

wherein the end effector is adapted to be placed in contact with a heart of a patient to create a channel.

9. The device of claim 8 further comprising a mounting device having a first end and a second end, the mounting device adapted to receive the ultrasonic vibration and to transmit the ultrasonic vibration from the first end to the second end, the first end of the mounting device coupled to the transducer assembly near an antinode.

10. The device of claim 8 further comprising a transmission rod having a first end and a second end, the transmission rod adapted to receive ultrasonic vibration and to transmit the ultrasonic vibration from the first end to the second end, the second end of the transmission rod coupled to the end effector near an antinode.

11. A surgical device for creating channels in a heart of a patient comprising:

a housing;

a transducer assembly carried by the housing; and

an end effector operatively coupled to the transducer assembly, the end effector having a vibrating channel-forming tip wherein the channel-forming tip is adapted to create channels in the heart of a patient.

12. The device of claim 11 wherein the device is configured for use in transmyocardial revascularization.

13. The device of claim 11 wherein the device is configured to create substantially constant diameter channels.

14. The device of claim 11 further comprising a viewing device to monitor the end effector.

15. A surgical device comprising:

a non-optical end effector; the end effector formed about an axial center line to create channels in selected tissue of a patient; and

a transducer assembly adapted to vibrate at an ultrasonic frequency in response to electrical energy wherein the transducer assembly actuates the end effector.

16. The device of claim 15 wherein the transducer assembly includes one of a piezoceramic transducer, magnetostrictive transducer, electromagnetic transducer, and electrostatic transducer.

17. The device of claim 15 wherein the end effector is configured symmetrically about the center line.

18. The device of claim 15 wherein the end effector includes a tip from the class containing a flat tip, a pointed tip, a tapered tip, a triangular tip, a hollow tabular tip, a hollow tubular tip, a cylindrically shaped tip and a cylindrical channel-forming tip.

19. The device of claim 15 wherein the end effector includes a first portion and a second portion;

the second portion extending from the first portion and having a smaller diameter than the first portion.

20. The device of claim 19 wherein the end effector includes a third portion extending from the second portion and having a smaller diameter than the second portion.

21. The device of claim 15 further including a control mechanism in communication with the transducer assembly to energize the surgical device.

22. The device of claim 15 wherein each channel-forming member is configured about an axial center line and the center lines extend parallel to one another.

23. A method of improving the blood flow to a heart of a patient comprising the steps of:

providing a surgical device having an end effector;

energizing the surgical device to cause the end effector to vibrate;

contacting the end effector with a ventricular wall of a heart;

advancing the end effector into the ventricle wall; and

creating a channel in the ventricular wall with the end effector.

24. A method as in claim 23 wherein the ventricular wall has an outer surface and an inner surface; and

wherein the channel starts at the outer surface and extends into the wall.

25. A method as in claim 23 wherein a plurality of channels are created substantially simultaneously in the ventricular wall.

26. A method of improving blood flow comprising the steps of

inserting an end effector into a patient;

placing a tip of the end effector in direct contact with a surface of the heart;

energizing the end effector to cause the tip to vibrate;

piercing through the surface of the heart with the tip to create a channel; and

removing the end effector.

27. The method of claim 26 wherein the surface of the heart is the outer wall of the heart.

FIG. 1

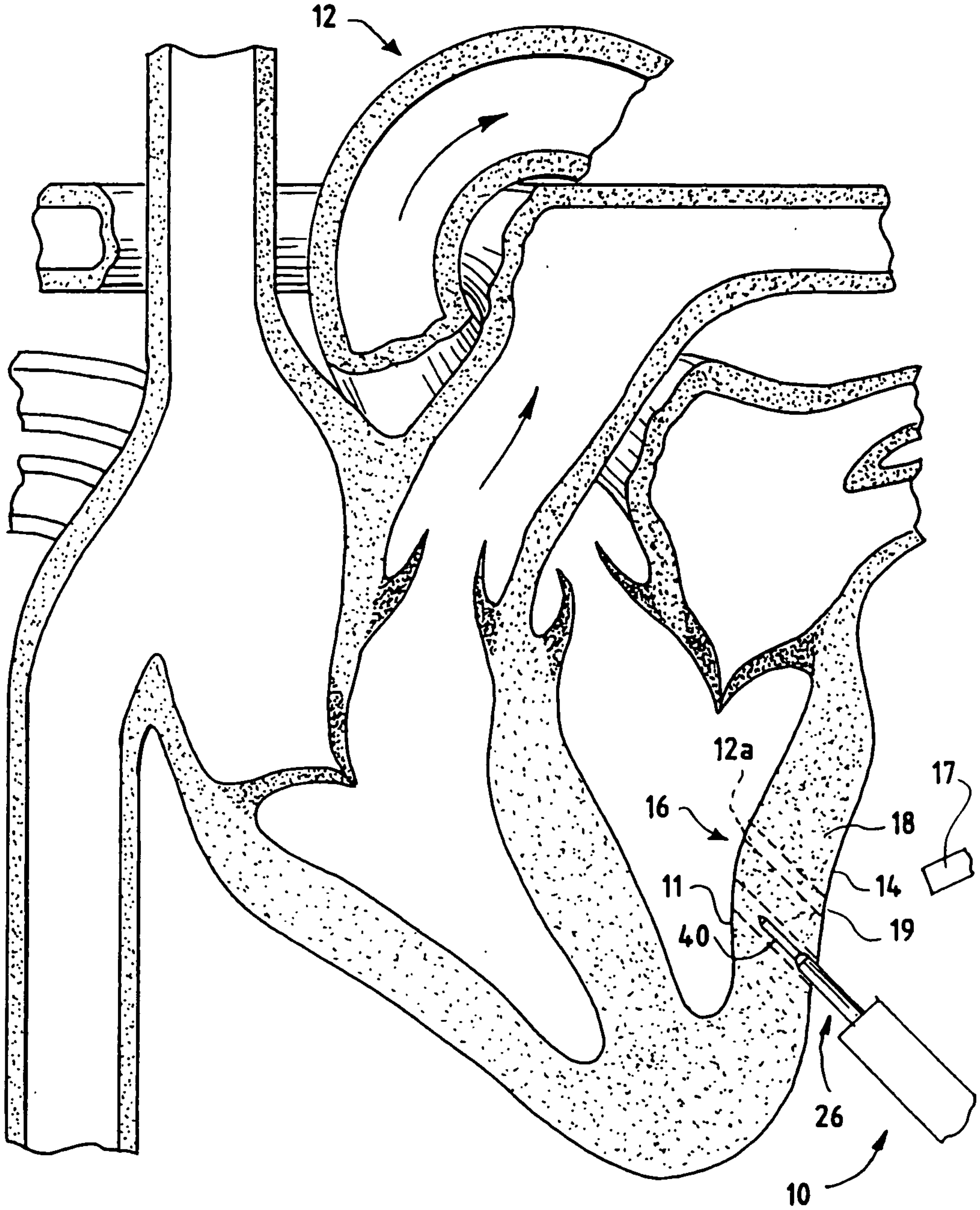

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FIG. 2

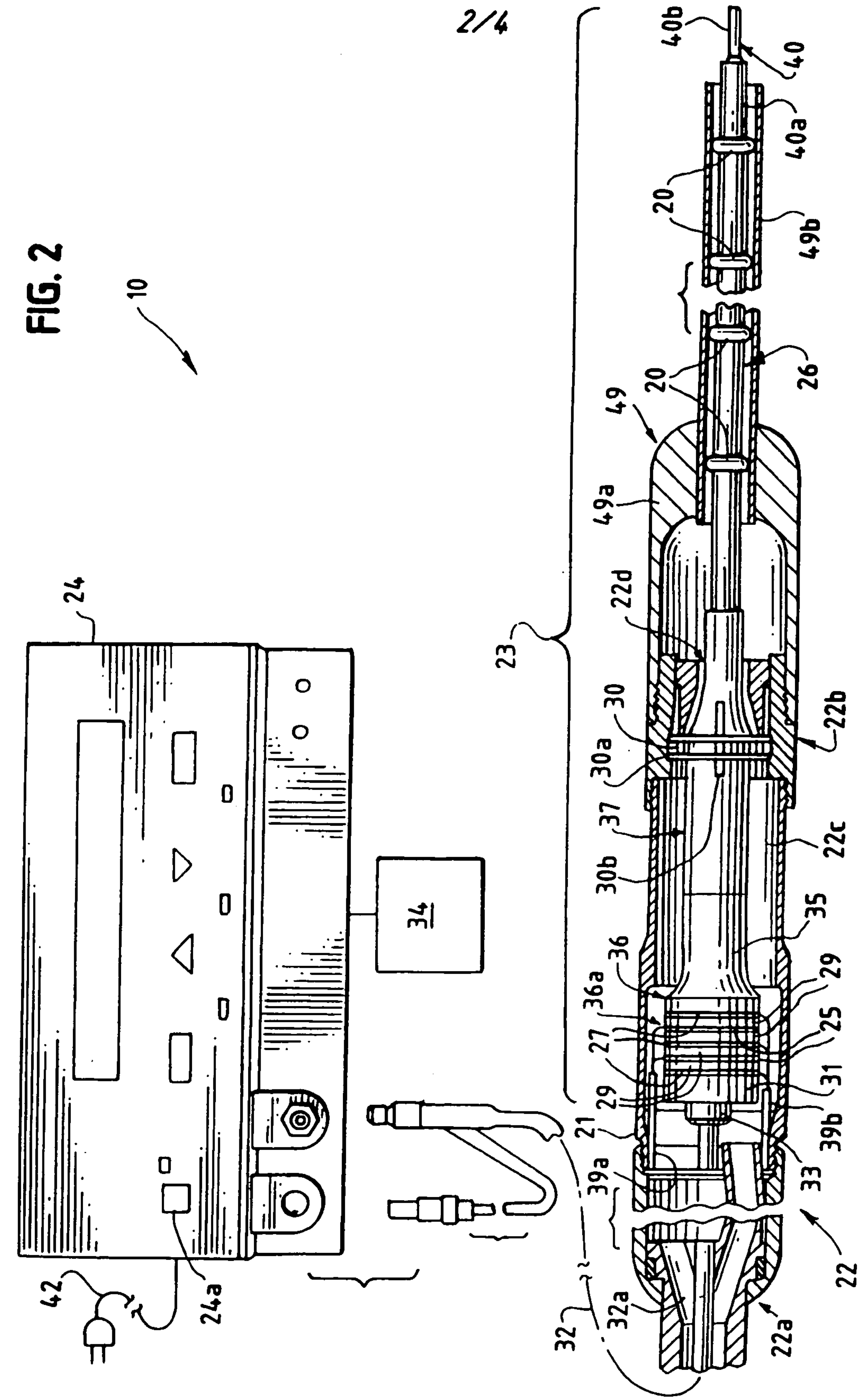
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FIG. 3

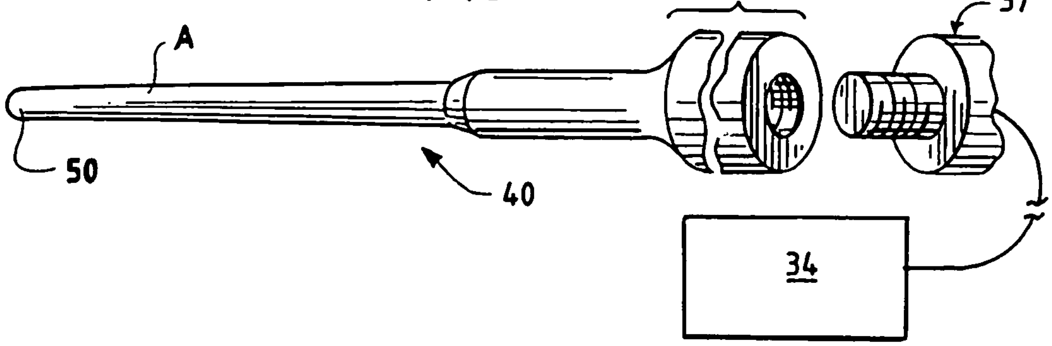


FIG. 4

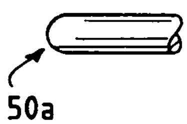


FIG. 5

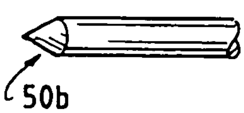


FIG. 6

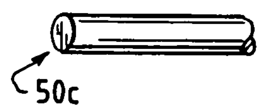


FIG. 7

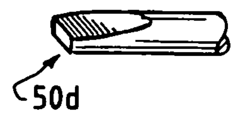


FIG. 8

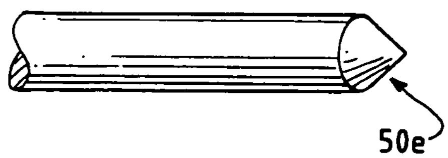


FIG. 9

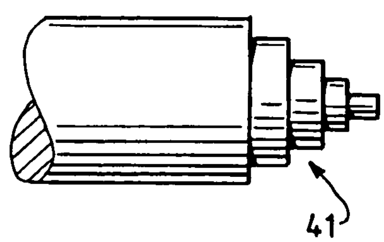


FIG. 10

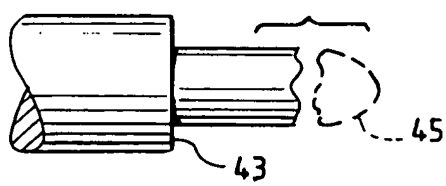


FIG. 11

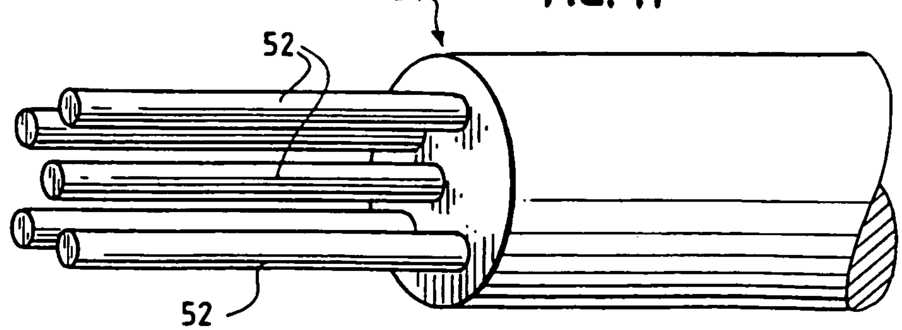


FIG. 12

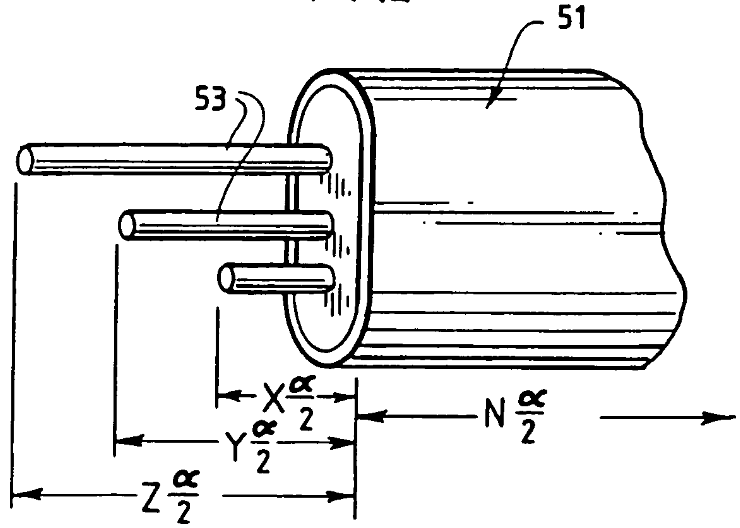
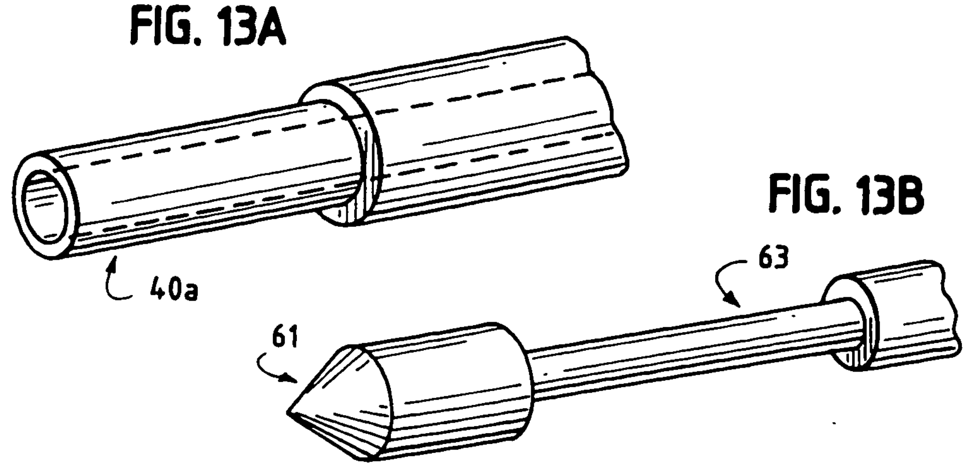


FIG. 13A

FIG. 13B



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/18543

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 624 346 A (ETHICON) 17 November 1994 cited in the application see column 3, line 57 - column 4, line 7	1-5,8-22
Y	US 4 920 954 A (ALLIGER ET AL.) 1 May 1990 see column 7, line 1-6 see column 12, line 36 - line 39	1-5,8-22
A	EP 0 394 583 A (SUMITOMO) 31 October 1990 see column 10, line 24-44; figure 16F	1,4,8,11
A	US 5 222 501 A (IDEKER ET AL.) 29 June 1993 see column 8, line 1-3	1,8,11
A	DE 22 19 790 A (POHLMAN) 31 October 1973 see page 3, paragraph 1; figure 1	4

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

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Date of the actual completion of the international search	Date of mailing of the international search report
29 January 1998	06.02.98

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Glas, J

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/18543

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,P	WO 96 34561 A (HEART RYTHM TECHNOLOGIES) 7 November 1996 see page 18, line 6-10 -----	1,8,11

4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 97/18543

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 6,7,23-27
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

In. .ational Application No
PCT/US 97/18543

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